



FEB 19 2013

510(k) Summary

SYBRON DENTAL SPECIALTIES

Submitter:

Sybron Dental Specialties, Inc.
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 Orange, California 92867
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 Colleen Boswell - Contact Person

Date Summary Prepared: November 2012

- Trade Name – *Nexus RMGI*
- Common Name – Luting Cement
- Classification Name – Dental Cement, per 21 CFR 872.3275(b)
- Product Codes – EMA

Devices for Which Substantial Equivalence is Claimed:

- *RelyX Luting Plus Automix*, 3M ESPE, K111185

Device Description

Nexus™ RMGI is a radiopaque resin-modified glass ionomer luting cement offered in a paste/paste formulation that provides an option for tack light-curing of excess cement. This dual-cure material consists of a base and a catalyst packaged in dual-barrel syringes. The base and catalyst are dispensed from the dual-barrel syringe through automix tips.

Indications for Use

Nexus RMGI is intended for use as a permanent dental cement. It is indicated for the following indirect restorations:

1. Cementation of metal-based inlays, onlays, crowns and bridges
2. Cementation of resin inlays, onlays, crowns and bridges
3. Cementation of all ceramic inlays
4. Cementation of high strength (zirconia based) all ceramic crowns and bridges
5. Cementation of metal, ceramic and fiber posts

Summary of Technological Characteristics

Descriptive Information	Nexus RMGI	RelyX Luting Plus Automix (K111185)
Company	Kerr Corporation	3M ESPE
Indication for Use	<p>Nexus RMGI is intended for use as a permanent dental cement. It is indicated for the following indirect restorations:</p> <ul style="list-style-type: none"> • Cementation of metal-based inlays, onlays, crowns and bridges • Cementation of resin inlays, onlays, crowns and bridges • Cementation of all ceramic inlays • Cementation of high strength (zirconia-based) all ceramic crowns and bridges • Cementation of metal, ceramic and fiber posts 	<p>This device is intended for use as a dental cement. RelyX™ Luting Plus Automix (LEXUS-2) is indicated for Luting:</p> <ul style="list-style-type: none"> • Luting porcelain fused to metal crown and bridges to tooth structure, amalgam, composite or glass ionomer core build ups • Luting metal inlays, onlays or crowns • Luting pre-fabricated and cast post cementation • Luting orthodontic appliances • Luting crowns made with all-alumina or all zirconia cores such as Procera® AllCeram
Gel Time (or Working Time) @ 22.5 ± 1.0°C	1'55"	3'20"
Set Time @ 22.5 ± 1.0°C	3'15"	6'45"
Set Time @ 37.0 ± 1.0°C	2'20"	4'45"
Flexural Strength (MPa) as per ISO 9917-2:2010	36.7	20.7
Compressive Strength (Mpa)	154	103
Filler Loading, wt. %	60.3	N/A
Translucency, %	39.1	16.1
Film Thickness, µm as per ISO 9917-2:2010	9	16

Descriptive Information	Nexus RMGI	RelyX Luting Plus Automix (K111185)
Consistency of mixed paste, cm	2.9	3.2
Radiopacity, % Al	217	150
Solubility (7 days), %	0.28	0.94
Cumulative Fluoride Release, ppm		
1 week	25.7	41
4 week	48.1	81.9
Shear Bond Strength to various substrates		
Dentin, MPa	20.2	15.6
Enamel (Bovine), MPa	16.2	10.5
Rexillum III, MPa	26.3	12.0
Gold Alloy, MPa	16.8	11.8
Zirconia (Lava), MPa	17.5	13.8
Porcelain (Vitablocs) with HF etch, MPa	23	14.3
Composite (Premise Indirect), MPa	17.6	7.3
Lithium Disilicate, MPa	17.7	14.9
Alumina, MPa	14.9	13.1
Titanium, MPa	25.2	13.4
Post, lbs	53.9	34.8

Non-Clinical Test Data

Biocompatibility studies were completed which demonstrate that the material is safe for its intended use. Nexus RMGI was tested through the following tests: ISO L929 MEM Elution Test, ISO Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay, ISO Intramuscular Implantation Test, ISO Kligman Maximization Test and ISO Oral Irritation Test.

The 510(k) submission also includes data from bench testing used to evaluate performance characteristics of *Nexus RMGI* as compared to the predicate device, RelyX Luting Plus Automix currently marketed by 3M ESPE. The characteristics evaluated include Work Time, Set Times, Flexural Strength, Compressive Strength, Filler Loading, Translucency, Film Thickness, Consistency of Mixed Paste, Radiopacity, Solubility, Fluoride Release and Bond Strength.

Clinical Test Data

Clinical testing has not been conducted on this product.

Conclusion

Based upon the biocompatibility tests and bench testing, the clinical performance of *Nexus RMGI* is deemed to be substantially equivalent to the RelyX Luting Plus Automix.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

February 19, 2013

Kerr Corporation
C/O Ms. Colleen Boswell
Director, Regulatory Affairs
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
ORANGE CA 92867

Re: K123595
Trade/Device Name: Nexus RMGI
Regulation Number: 21 CFR 872.3275(b)
Regulation Name: Dental Cement
Regulatory Class: II
Product Codes: EMA
Dated: November 19, 2012
Received: November 21, 2012

Dear Ms. Boswell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (If known): K123595

Device Name: *Nexus RMGI*

Indications for Use:

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner
Sean Runner, DDS, MA
2013.02.19 15:38:46
05:00

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K123595